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K003567

2.

510(k) SUMMARY
of Safety and Effectiveness
+
SE Comparison Table

Corinthian Medical Ltd.
As required by Section 807.92

2.1 Submitter: [807.92 (a)(1)]

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2.2 Contact Person: [807.92 (a)(1)]

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2.3 Date Summary Prepared: [807.92 (a)(1)]
November 10, 2000

2.4 Device Names: [807.92 (a)(2)]

Proprietary	SerenoCem™
Common	Glass Ionomer Bone Cement
Classification	Cement, Bone, Glass Ionomer

2.5 Reason for Submission: [807.81(2)]

New Device

2.6 Predicate Device [807.92(a)(3)]

Manufacturer	**Espe Dental-Medizin GmbH & Co. KG**
FDA Clearance	**K 973262**
Proprietary Name	KETAC-FIL APLICAP PLUS
Catalog #'s	055000 – 055100

2.7 Device Description: [807.92(a)(4)]

SerenoCem™ is a novel hybrid glass polymer composite consisting of an alkaline inorganic glass reacted with organic polyacid. The setting occurs without exotherm to lock the glass particles in an insoluble hydrogel matrix held together by a combination of ionic cross-links, hydrogen bridges and chain entanglements. As the setting does not generate heat, it does not cause thermal damage to tissue at the implant site. Upon setting, SerenoCem™ chemically bonds to bone mineral (apatite) and metals. It does not undergo appreciable shrinkage as a result of the gelation and setting reaction.

SerenoCem™ is a conventional GIC that has been optimized for use as a bone cement for specific otologic applications.

In terms of general chemical composition, SerenoCem™ is **substantially equivalent** to SE devices.

2.8 Intended Use: [807.92 (a)(5)]

SerenoCem™ is designed for non-weight bearing applications in otologic surgery, such as:

1. The reconstruction of the ossicular chain where the cement can be used to repair bony ossicles in their normal position;

2. Acoustic meatal wall reconstruction in well-ventilated middle ears;

3. Cementation of cochlear implants.

The indications for use are **different** from SE device:
SerenoCem™ = **Otologic** vs Ketac-Fil *Plus* Aplicap = **Dental**

The safety and effectiveness in their respective applications, if user instructions are strictly adhered to, is **substantially equivalent.**

2.9 Differences in Formulation and Method of Preparation when Compared to SE Devices [807.92 (a)(6)]

2.9.1 Formulation Components:

Glass: SerenoCem™ utilizes a special glass that was selected from over 100 different compositions on the basis of in vitro and in vivo biocompatibility testing.
Powder-Liquid Ratio: Adjusted for specific viscosity required for middle ear procedures.
Pigments/Colorants: SerenoCem™ contains no pigments/ colorants whatsoever, while SE device is offered in eight (8) shades ranging from light to dark-grey.

Nevertheless, SerenoCem™ is **substantially equivalent** to SE device, as both are produced by combining an acid degradable glass powder, a polymeric acid, and water.

2.9.2 Packaging – Preparation for Surgery

Like the SE device, SerenoCem™ is sold capsulated. Immediately prior to use, cement is mixed in manufacturer-recommended mixer for 10 seconds, then transferred to applicator and onto surgical/dental site.

Product packaging/preparation is **substantially equivalent.**

2.9.3 Sterility

Contrary to SE device, SerenoCem™ is sold sterile (gamma irradiation).
SERENO*cem* = otologic application = **sterile**
KETAC-Fil *Plus* Aplicap = dental application = **non-sterile**

2.10 Discussion of Safety and Effectiveness [807.92(b)]

Clinical investigations and in vivo applications of SerenoCem™ have proven the product to be as safe and effective for its otologic indications – if used as labeled – as SE device is for dental applications.

2.10.1 Biocompatibility

In vitro and *in vivo* clinical investigations have shown SerenoCem™ to be a highly biocompatible bone substitute in non-load bearing middle ear applications when applied

1. in dry surgical field; and
2. away from nerves, neural tissues, brain dura and other parts of the central nervous system (no acoustic neuroma or skull base surgery!).

The biocompatibility of SerenoCem™ in the set state is **substantially equivalent** in the otologic environment to that of SE device in dental applications.

2.10.2 Audiological Results

Audiological results achieved with SerenoCem™are substantially equivalent if not superior to those with ossicular prosthesis implants made of other materials.

2.10.3 Long-Term Stability

As SerenoCem™ behaves like bone in the set state, long-term patient benefits should be excellent. All published data on clinical evidence with other GIC's during the past 10 years support this expectation. During CE certification by an accredited third-party certification agency[1], it was determined that CORINTHIAN should maintain manufacturing and related product records for a period of fifty (50) years as ossicular and meatal wall reconstructions are expected to stay in situ for the patients' remaining life. [2]

Compared to predicate devices, SerenoCem's long-term stability appears to be **Significantly Higher** than is possible with SE device in oral/dental environment.

2.10.4 MRI

SerenoCem™ has no magnetic properties and will not generate heat when exposed to nuclear magnetic resonance tomographs. Comparable to SE device, radiopacity is comparable to bone.

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1 SGS United Kingdom Ltd., Camberley GU15 3EY, England, is an active participant in the mutual confidence-building period required for recognition as a Conformity Assessment Body (CAB).

2 Cochlear implants, by comparison, have an average life span of 15 years.

If SerenoCem™ is used for the cementation of cochlear implants, the manufacturers' instructions (Warning Statements) for these devices must be followed.[3]

2.11 Industry Standards: [807.92 (d)]

Like SE manufacturer, CORINTHIAN certifies compliance with required ISO/EN/ASTM/AAMI/ANSI and other product-related standards that apply to the manufacture, sterilization, packaging, and labeling of subject devices including the validation of these processes: **Substantially Equivalent**

2.12 Information Bearing on the Safety and Effectiveness: [807.92 (b)(3)]

CORINTHIAN's SerenoCem™ is formulated of substantially equivalent components than SE device. The indications for use are different (otologic vs. dental), but extensive in vitro and in vivo (published) biocompatibility studies have proven the safety and effectiveness of their applications – if user instructions are strictly followed – to be substantially equivalent. Long-term stability of otologic non-weight bearing applications is significantly higher than what can be expected in the more active/chemically agressive dental environment.

The results of design validation and clinical testing raise no additional issues of safety and effectiveness.

[3] Cochlear implants require the warning statement that affected patients ARE NOT TO BE EXPOSED TO MRI!

2.13 COMPARISON WITH PREDICATE DEVICE (TABLE)

Manufacturer	CORINTHIAN OTOLOGIC	ESPE DENTAL
Device	**SerenoCem™**	**Ketac®-Fil *Plus* Aplicap®**
Model	BC 010	055000 – 055100
Intended Use	Non-weight bearing applications in otologic surgery, such as: 1. Reconstruction of ossicular chain where cement can be used to repair bony ossicles in their normal position; 2. acoustic meatal wall reconstruction in well-ventilated middle ears; 3. cementation of cochlear implants.	Dental restorations including: 1. sealing endodontically treated root canals in single gutta-percha cone technique or multiple gutta-percha points in standard vertical or lateral-condensation method; 2. fixation of dental devices such as crowns and bridges; 3. application to tooth for protection of tooth pulp; 4. permanent dental cement or filling material.
Formulation	Glass polymer composite consisting of alkaline inorganic glass reacted with acrylic acid polymer.	Glass ionomer composite consisting of alkaline inorganic glass reacted with acrylic-maleic acid copolymer.
Pigments/Colorants	None	8 Shades (Pigments confidential)
Contraindications + Caution Statements	1. **Do not Use SerenoCem™** - for load-bearing applications; - in soft tissue and on cartilage without bone contact; - **in acoustic neuroma or skull base surgery or in any surgery where cement may come in contact with CSF.** 2. WHILE IN NON-SOLID STATE, do not place in direct contact with inner ear liquids, facial or cranial nerves, neural tissues, brain dura or other parts of the CNS as this may cause irreversible blockage of nerve conduction. Cover operating site with fascia if there is the slightest chance that free CNS structures may be exposed; 3. Keep operating field strictly dry during cement setting time (approx. 10 min.)	None labeled
Single Use Device	Yes	**Yes**
Long-Term Stability	Expected to remain stable for patient's remaining life or approx. 50 years	Average of 5 years
Users	Certified Otologic Surgeons	Dental Practitioners and Endodontists

	CORINTHIAN	ESPE
Biocompatible	Yes - In Solid State	Yes – In Solid State
Interactions **MRI**	1. MRI-compatible; image quality may be impeded in direct vicinity of implant; radiopacity is comparable to bone; 2. Patients with cochlear implants SHALL NOT BE EXPOSED TO MRI !	1. MRI-compatible
Microwave	Safe	Safe
Drugs	No interaction observed to date	Not labeled

Sterilization **Provided Sterile**	Yes	No
Sterilization Method	Gamma Irradiation	None Required
Resterilization	Not Permitted	Not Applicable

Packaging	Double Foil Package around capsule - to protect sterility; - to prevent accidental piercing and drying out of cement	Blister Packs around capsules
Packaging Units/Weights	0.75 g (approx.) per capsule	0.75 g (approx.) per capsule
Instructions for Use	**Notes:** **i.** For maximum working time, refrigerate cement at 2 – 8° C for 30 min. prior to use; **ii.** Cement setting time depends on OR temperature; indicated times are based on ambient temperature of 23° C. 1. Mix cement full 10 seconds with manufacturer-recommended mixer; 2. Insert capsule into applier and dispense onto dry glass surface; 3. Collect required amount with small otologic elevator and place in dry surgical field within 1-3 minutes after activation; 4. Place directly on ossicular or bony surface avoiding ALL contact with blood, inner ear liquids, or soft/ neural tissues until set (approx. 10 min.); 5. If there is the slightest chance of free CNS structures being exposed, interpose autologous bone paté or similar between raw area and ionomeric surface; 6. If necessary – within 3-4 min. after activation - lay cement down in subsequent layers; 7. Use minimum amount of cement required; trim/aspirate excess immediately;	1. Use manufacturer-recommended mixer; 2. Activate KETAC-FIL *PLUS* APLICAP in activator for 2 sec.; 3. Mix 8 – 10 seconds (depending on mixing device used); 4. Insert capsule into applier and dispense; 5. Working time (incl. mixing): 1 ½ minutes; 6. Setting time (from start of mixing): 7 minutes

	CORINTHIAN	ESPE
	8. Maintain dry operating site throughout procedure and setting time using swabs, suction, etc. (approx. 10 min.); 9. If necessary, shape carefully after setting with diamond bur under irrigation. Use reduced drill speed and do not exert pressure on work surface, as cement does not reach full strength for several hours; 10. Flush off resulting cement powder, avoiding all contact with soft tissues;	
Storage	1. Store in unopened, original package in dry, protected storage unit between 15-23° C; 2. Remove items that have reached their expiration date.	Store in dry, protected storage unit between 15 - 23° C
Accessories	1. Applicator 2. Mixer (110 V)	1. Activator 2. Mixers a. ROTOMIX: 8 sec. b. CAPMIX: 10 sec. 3. Applicator 4. Ketac-Conditioner 5. Application Tips

Nov. 13. 2000

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 12 2001

Dagmar S. Mäser
FDA Liaison for Corinthian Medical Ltd.
Business Support International
Amstel 320-I
1017 AP Amsterdam
The Netherlands

Re: K003567
Trade Name: SeronoCem™ Otologic Bone Cement
Regulatory Class: II
Product Code: 76 NEA
Dated: November 15, 2000
Received: November 20, 2000

Dear Mr. Mäser:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-6413. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

A. Ralph Rosenthal

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

510(k) Number K003567

Device Name **SerenoCem™**

INDICATIONS FOR USE

SerenoCem™ is designed for non-weight bearing applications in otologic surgery, such as:

1. the reconstruction of the ossicular chain where the cement can be used to repair the bony ossicles in their normal position;
2. acoustic meatal wall reconstruction in well-ventilated middle ears and
3. cementation of cochlear implants.

Description

SerenoCem™ is a reaction-bonded polymer composite formed by the neutralization gelation of a basic inorganic ionomer and an organic polyelectrolyte (polyacrylic) acid. To assure consistency of results, SerenoCem™ components are sold capsulated for mixing according to predetermined ratios.

Users

SerenoCem™ is intended for exclusive use by licensed otologic surgeons.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____

(Per CFR 801 109)

(Optional Format 1-2-96)

18-Oct-00

(Division Sign-Off)
Division of Ophthalmic Devices

510(k) Number K003567